510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Medical Co., Ltd.
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Contact: Yi Liu
Date of Application: 09/30/2009

2.0 Device information

Trade name: AG-695 Single Blood Glucose Monitoring System
AG-695 Multi Blood Glucose Monitoring System
AG-696 Single Blood Glucose Monitoring System
AG-696 Multi Blood Glucose Monitoring System
Common name: Blood Glucose Monitoring System
Classification name: Blood Glucose Monitoring System

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

4.0 Predict device information

Manufacturer: Andon Health Co., Ltd.
Device: AG-606 Blood Glucose Monitoring System
510(k) number: k073030

5.0 Intended use

5.1 AG-695 Single Blood Glucose Monitoring System

The AG-695 Single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip.. The AG-695 Single Blood Glucose

Monitoring System is intended to be used by a single person and should not be shared.

The AG-695 Single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-695 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 single Blood Glucose Test Strips are for use with the AG-695 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

5.2 AG-695 MULTI Blood Glucose Monitoring System

The AG-695 MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip.. The AG-695 MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of diabetes control.

The AG-695 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 MULTI Blood Glucose Test Strips are for use with the AG-695 MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

This system should only be used with single-use, auto-disabling lancing devices.

5.3 AG-696 Single Blood Glucose Monitoring System

The AG-696 Single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip. The AG-696 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-696 Single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-696 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 single Blood Glucose Test Strips are for use with the AG-696 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

5.4 AG-696 MULTI Blood Glucose Monitoring System

The AG-696 MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip. The AG-696 MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of diabetes control.

The AG-696 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 MULTI Blood Glucose Test Strips are for use with the AG-696 MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

This system should only be used with single-use, auto-disabling lancing devices.

6.0 Device description

The four blood Glucose Monitoring system AG-695 Single, AG-695 MULTI, AG-696 Single and AG-696 MILTI are all based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. All of them use the same technological characteristics for testing but the appearance is different from their predicate device. More over, all of the four systems have a voice function.

7.0 Summary comparing technological characteristics with predicate device

7.1 AG-695 Single and AG-695 MULTI Blood Glucose Monitoring System

Similarities		
CHARACTERISTICS	NEW DEVICE: AG-695 Single and AG-695 MULTI Blood Glucose Monitoring System	PREDICATE: AG-606 Blood Glucose Monitoring System (K073030)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	30-55%	30-55%
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Dimensions	52mmx 92mmx 21mm	82mmx 59mmx 20mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	350 times with time and date displaying	350 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3V (2 AAA)	DC 3V (2 AAA)
Battery Life	Approx. 1000 normal tests	Approx. 1000 normal tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1000 Single Test Strip for AG-695 Single BGMS AGS-1000 MULTI Test strip for AG-695 MULTI BGMS	AGS-600 Test Strip
Sample Volume	Minimum 0.7 microliter	Minimum 1 microliter
Other function	Voice function	N/A

7.2 AG-696 Single and MULTI Blood Glucose Monitoring System

CHARACTERISTICS	NEW DEVICE: AG-696 Single and AG-696 MULTI Blood Glucose Monitoring System	PREDICATE: AG-606 Blood Glucose Monitoring System (K073030)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	30-55%	30-55%
Operating Temperature Range	10℃~40℃(50°-104°F)	10℃~40℃(50°-104°F)
Dimensions	90mmx 59mmx 22mm	82mmx 59mmx 20mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	500 times with time and date displaying	350 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC3V (2XAAA batteries)	DC 3V (2 AAA)
Battery Life	Approx. 1000 normal tests	Approx. 1000 normal tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1000 Single Test Strip for AG-696 Single BGMS AGS-1000 MULTI Test strip for AG-696 MULTI BGMS	AGS-600 Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 1 microliter
Other function	voice function	N/A

8.0 Performance summary

AG-695 Single BGMS, AG-695 MULTI BGMS, AG-696 Single BGMS and AG-696 MULTI BGMS conform to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- FDA Draft Guidance Document-Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems: October 24, 2006
- Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated to clean and disinfect the BGMS, and the performance and material will not be effected by the disinfection during the BGMS' lifetime.

9.0 Comparison to the predict device and the conclusion

The four blood glucose monitor AG-695 Single AG-695 MULTI, AG-696 Single and AG-696 MULTI are very similar with the predicate device AG-606, their appearance is different from AG-606, they use the different test strips, they also has a new voice function. And the intended use of AG-695 MULTI and AG-696 MULTI are also different from their predicate device.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Andon Medical Co., Ltd.
c/o Yi Liu
No. 04-23-3 Airport Industrial Park
Tianjin, China 300381

JUL 15 2011

Re: k093755
Trade name: AG-695 Single Blood Glucose Monitoring System
AG-695 Multi Blood Glucose Monitoring System
AG-696 Single Blood Glucose Monitoring System
AG-696 Multi Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: July 13, 2011
Received: July 13, 2011

Dear Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K093755

Device Name: AG-695 Single Blood Glucose Monitoring System

Indication for Use:

The AG-695 Single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip.. The AG-695 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-695 Single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-695 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 single Blood Glucose Test Strips are for use with the AG-695 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Ruth Chesler

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093755

Indication for Use

510(k) Number (if known): K093755

Device Name: AG-695 MULTI Blood Glucose Monitoring System

Indication for Use:

The AG-695 MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip.. The AG-695 MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of diabetes control.

The AG-695 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 MULTI Blood Glucose Test Strips are for use with the AG-695 MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

This system should only be used with single-use, auto-disabling lancing devices.

Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Indication for Use

510(k) Number (if known): **K093755**

Device Name: AG-696 Single Blood Glucose Monitoring System

Indication for Use:

The AG-696 Single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip. The AG-696 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-696 Single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-696 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 single Blood Glucose Test Strips are for use with the AG-696 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Evaluation and Safety

510(k) K093755

Indication for Use

510(k) Number (if known): K093755

Device Name: AG-696 MULTI Blood Glucose Monitoring System

Indication for Use:

The AG-696 MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample from the fingertip. The AG-696 MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of diabetes control.

The AG-696 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The AGS-1000 MULTI Blood Glucose Test Strips are for use with the AG-696 MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

This system should only be used with single-use, auto-disabling lancing devices.

Prescription Use ✓ And/Or Over the Counter Use ✓

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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